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No. 96-766

In the Supreme Court of the United States

OCTOBER TERM, 1996

ARGENT CHEMICAL LABORATORIES, INC., ETC.,
PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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19 pp

QUESTION PRESENTED

Whether the seizure of veterinary drugs pursuant to a warrant for arrest *in rem* issued by the district court in conformity with the procedures outlined in the Federal Food, Drug, and Cosmetic Act and the Supplemental Rules for Certain Admiralty and Maritime Claims, after an uncontested warrantless inspection of petitioner's premises, violates the Fourth Amendment.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A14) is reported at 93 F.2d 572. The opinion of the district court (Pet. App. B1-B10) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 16, 1996. The petition for a writ of certiorari was filed on November 14, 1996. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits persons from adulterating medical or veterinary drugs in interstate commerce, and from selling or receiving such drugs that have been adul-

terated. 21 U.S.C. 331(a)-(c). The FDCA expressly provides that any article of a drug that has been adulterated "shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States * * * within the jurisdiction of which the article is found." 21 U.S.C. 334(a)(1). The statute further states that "[t]he article * * * proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty." 21 U.S.C. 334(b).

The Supplemental Rules for Certain Admiralty and Maritime Claims (Supplemental Rules) "apply to the procedure in statutory condemnation proceedings analogous to maritime actions in rem, whether within the admiralty and maritime jurisdiction or not." Admiralty Suppl. R. A. Under the Supplemental Rules, an action in rem may be brought "[w]henever a statute of the United States provides for a maritime action in rem or a proceeding analogous thereto." Admiralty Suppl. R. C(1)(b). Such an action is commenced by a complaint, which must "be verified on oath or solemn affirmation," and which must "describe with reasonable particularity the property that is the subject of the action." Admiralty Suppl. R. C(2).

The Supplemental Rules require prior judicial review of the complaint before the issuance of a warrant for arrest of the property subject to the action, "[e]xcept in actions by the United States for forfeitures for federal statutory violations." Admiralty Suppl. R. C(3). Where an action by the United States for a forfeiture for a federal statutory violation is involved,

the Supplemental Rules explicitly provide that the "the clerk, upon filing of the complaint, shall forthwith issue a summons and warrant for the arrest of the vessel or other property without requiring a certification of exigent circumstances." *Ibid.*

2. Petitioner Argent Chemical Laboratories is engaged in the business of manufacturing and repackaging veterinary drugs. Pet. App. A2. On July 29, 1994, as the result of several FDA inspections of petitioner's facilities, the United States obtained a warrant for arrest of certain of petitioner's drugs from the deputy clerk of the United States District Court for the Western District of Washington, in accordance with the Supplemental Rules. Pet. App. A2-A3; Pet. 3.

Petitioner filed a motion to quash the government's warrant on the ground that the seizure of its drugs without a prior judicial warrant violated the Fourth Amendment. Pet. App. A3. The district court granted petitioner's motion, concluding that, notwithstanding the FDCA and the Supplemental Rules, the government was required by the Fourth Amendment to "obtain[] a warrant based upon probable cause and authorized by a detached judicial officer." *Id.* at B9. It therefore ordered the seized drugs returned to petitioner. *Ibid.*

3. The court of appeals reversed. Pet. App. A1-A14. After reviewing this Court's cases dealing with Fourth Amendment protections applicable to "closely regulated" businesses, see *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72 (1970); *United States* v. *Biswell*, 406 U.S. 311 (1972), the court concluded that the seizure of petitioner's drugs did not violate the Fourth Amendment. Pet. App. A14.

The court first reviewed the extensive regulations applicable to the preparation, packaging and promotion of animal drugs (Pet. App. A6-A7), and concluded that the veterinary drug industry is "closely regulated" under *Colonnade-Biswell*. The court also found that the other criteria for application of the *Colonnade-Biswell* doctrine had been met: (1) the government has a "substantial interest" in regulating the safety and effectiveness of animal drugs, (2) warrantless searches and seizures further the regulatory scheme by deterring violations of regulatory requirements and removing nonconforming products from the marketplace, and (3) by advising the commercial owner that the premises are subject to search, while at the same time limiting the scope of that search, the statute and the Supplemental Rules "provide a constitutionally adequate substitute for a warrant." *Id.* at A8-A9. See generally *New York* v. *Burger*, 482 U.S. 691, 701-702 (1987).

The court of appeals rejected as "untenable" petitioner's contention that the *Colonnade-Biswell* doctrine applies only to inspections and not to seizures, observing that decisions of this Court have applied the exception to "seizures of contraband discovered during the unwarranted inspections," and have "approved the use of evidence seized in the course of the inspection." Pet. App. A10. The court also "attach[ed] no significance" to the fact that the warrant for arrest of petitioner's drugs was executed "some time after" the FDA's last inspection of petitioner's premises. *Id.* at A13. "If a random, unannounced inspection does not violate [petitioner's] Fourth Amendment rights of privacy," the court stated, "we see no reason why the unannounced execution of a warrant under the Supplemental Rules

would do so." *Ibid.* In short, the court concluded, because the seizure of petitioner's drugs was from "the premises of a closely regulated manufacturer" and was "conducted within the regulatory scheme in the manner Congress has authorized," there was "no need to brigade the seizure with an inspection in order to legitimize it." *Ibid.*

ARGUMENT

The decision below is correct and does not conflict with the decision of any other court of appeals. This case thus does not warrant further review.

1. Although the Fourth Amendment's protections apply to commercial as well as residential premises, see, *e.g.*, *See* v. *City of Seattle*, 387 U.S. 541, 545-546 (1967), "a business, by its special nature and voluntary existence, may open itself to intrusions that would not be permissible in a purely private context." *G.M. Leasing Corp.* v. *United States*, 429 U.S. 338, 353 (1977). Thus, a judicial warrant is not always required when the government seeks to conduct a search of a business "long subject to close supervision and inspection," *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72, 77 (1970), or that has been "pervasively regulated." *United States* v. *Biswell*, 406 U.S. 311, 316 (1972).

The so-called *Colonnade-Biswell* exception to the Fourth Amendment's judicial warrant requirement derives from the fact that owners of commercial property subject to comprehensive government supervision have a "reduced expectation of privacy," *New York* v. *Burger*, 482 U.S. 691, 702 (1987), and "an inspection program may in some cases be a necessary component of federal regulation." *Donovan* v. *Dewey*, 452 U.S. 594, 599 (1981). Under the exception,

the government may conduct a search of a "closely regulated" commercial business without a warrant if three criteria are met. *Burger*, 482 U.S. at 702. First, the regulatory scheme authorizing the warrantless inspection must be supported by a "substantial" government interest. *Ibid.* Second, warrantless inspections must be "necessary to further [the] regulatory scheme." *Ibid.* Third, "the statute's inspection program, in terms of the certainty and regularity of its application, [must] provid[e] a constitutionally adequate substitute for a warrant." *Id.* at 703.

The *Colonnade-Biswell* exception applies to seizures as well as searches, as the court of appeals recognized. Pet. App. A10. *Colonnade* itself was a suit for return of "seized liquor," 397 U.S. at 72, and this Court there took care to emphasize Congress's "broad authority to fashion standards of reasonableness for *searches and seizures*" in the liquor industry. *Id.* at 77 (emphasis added). Similarly, in *Biswell*, the issue involved the admissibility of two unlicensed firearms that had been seized during a warrantless search. See 406 U.S. at 312. Moreover, the Fourth Amendment is concerned with "reasonable expectations of privacy." *Katz* v. *United States*, 389 U.S. 347, 361 (1967) (Harlan, J., concurring); see *Burger*, 482 U.S. at 699-701. In the present context, the intrusion on an owner's privacy expectations is no greater from the government's seizure of commercial goods than from the government's inspection of the same items. See *Minnesota* v. *Dickerson*, 508 U.S. 366, 377 (1993) ("The seizure of an item whose identity is already known occasions no further invasion of privacy"); see also *Skinner* v. *Railway Labor Executives' Ass'n*, 489 U.S. 602, 618 n.4 (1989) ("It is not necessary to our

analysis * * * to characterize the taking of * * * samples as a seizure * * *, for the privacy expectations protected by this characterization are adequately taken into account by our conclusion that such intrusions are searches").[1]

2. The *in rem* seizure of petitioner's drugs did not violate the Fourth Amendment under the *Colonnade-Biswell* principles. Businesses engaged in the manufacture, packaging and storage of human and animal drugs plainly are "closely regulated" within the meaning of the *Colonnade-Biswell* exception. *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 537 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982). The FDCA, as well as the FDA's regulations promulgated thereunder, regulate "virtually every phase of the drug industry * * * from packaging, labeling and certification of expiration dates, to prior FDA approval before new drugs can be marketed." 651 F.2d at 537 (footnote omitted). See, *e.g.*, 21 U.S.C. 351(a) (regulating manufacture), 21 U.S.C. 351(b) (regulating strength and purity), 21 U.S.C. 352(a), (b), (f), (g), (h) and (p) (packaging and labeling), 21 U.S.C. 355 (new drug approvals); 360b

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[1] Of course, a seizure affects a claimant's *possessory* interests in a way that an inspection does not. See *Horton* v. *California*, 496 U.S. 128, 133 (1990). But a claimant's possessory interests in alleged contraband do not override the public's interest in having potentially hazardous or ineffective drugs removed temporarily from the stream of commerce. See *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601 (1950). And the claimant is fully protected against being permanently dispossessed of its goods by the statutorily-protected opportunity to contest the government's action for permanent forfeiture. See 21 U.S.C. 334; Admiralty Suppl. R. C; *Ewing*, 339 U.S. at 598.

(new animal drug approvals); 21 C.F.R. Pts. 200-599. As a company engaged in the manufacture, packaging and storage of veterinary drugs, petitioner operates in a business long subject to pervasive and comprehensive government regulation. Pet. App. A7-A8 & n.3

There can also be little doubt that the regulatory scheme governing the drug industry furthers a substantial government interest. See *Burger*, 482 U.S. at 702. Drugs intended to treat diseases in human beings that are manufactured, packaged or stored without proper safeguards pose an obvious health and safety risk to those who use them, for in the absence of compliance with regulatory standards, there can be no assurance that the drug is safe for its intended use, or "has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. 351(a)(2)(B). The government similarly has a substantial interest in the safety and effectiveness of animal drugs since unsafe or ineffective animal drugs pose a serious risk to the health and safety of the animals for whom they are prescribed. Indeed, unsafe or ineffective animal drugs may pose a significant risk to human health, when the diseases for which they are prescribed affect animals destined for human consumption. See *United States* v. *9/1 KG Containers*, 854 F.2d 173, 174 (7th Cir. 1988), cert. denied, 489 U.S. 1010 (1989). In short, as the court of appeals concluded, whether the government's interest in the safety and effectiveness of animal drugs "is human health, economic health, or both * * * it is substantial." Pet. App. A8.

The authority to seize adulterated goods without a judicial warrant is also a necessary aspect of the regulatory scheme governing the preparation, pack-

aging and storage of human and animal drugs. See *Burger*, 482 U.S. at 709-710. A drug that has been improperly manufactured, packaged, or stored, or as to which there is no documentation that regulatory standards have been followed, poses an obvious risk to the physical—and economic—health and safety of those who would use it. Eliminating that threat is not simply a matter of determining that a regulatory violation has occurred, and imposing a penalty or other sanction on the manufacturer. To eliminate the threat to the public the offending drugs must be removed from the marketplace. See Pet. App. A9. Drugs are easily sold, and there may be few means—apart from strict compliance with the FDCA's requirements—for a consumer to know whether the drug he or she has purchased is safe and effective for its intended use. See *United States* v. *Dotterweich*, 320 U.S. 277, 285 (1943).

Finally, the FDCA and the Supplemental Rules provide a "constitutionally adequate substitute for a warrant." *Burger*, 482 U.S. at 711. See Pet. App. A9. The FDCA expressly informs those who manufacture, package or store human or animal drugs that adulterated or misbranded drugs "shall be liable to be proceeded against * * * on libel of information and condemned" in federal district court, 21 U.S.C. 334(a)(1), in accordance with procedures that "conform, as nearly as may be, to the procedure in admiralty." 21 U.S.C. 334(b). Thus, petitioner could not "help but be aware" that its drugs would be subject to seizure if they proved adulterated. *Dewey*, 452 U.S. at 600; see also *Skinner*, 489 U.S. at 622. The FDCA also "narrowly define[s]" the scope of the seizures it authorizes. See *Burger*, 482 U.S. at 711. Government officials are empowered to seize only those drugs that

are "adulterated or misbranded," 21 U.S.C. 334(a)(1), terms that the statute defines in detail. See, *e.g.*, 21 U.S.C. 351, 352. Moreover, consistent with the Fourth Amendment's admonition that "the persons or things to be seized" must be "particularly described," U.S. Const. Amend. IV, the Supplemental Rules require that the complaint that commences an action to enforce a forfeiture for federal statutory violations "shall describe with reasonable particularity the property that is the subject of the action and state that it is within the district or will be during the pendency of the action," as well as stating "the place of seizure." Admiralty Suppl. R. C(2).[2] Like the Fourth Amendment, moreover, the Supplemental Rules provide that the government's complaint for forfeiture "shall be verified on oath or solemn affirmation." *Ibid.* Finally, a decision to commence a forfeiture action is not lightly undertaken. As the court of appeals recognized, in most cases one of FDA's 21 district offices, the appropriate FDA Center in headquarters, the agency's Office of Enforcement, as well as the Office of Chief Counsel and the Department of Justice all review the merits of a case before a seizure is recommended. Pet. App. A9-A10 (citing *FDA Regulatory Practices Manual*, Ch. 6, at 173-185 (Aug. 1995)). See *Ewing*, 339 U.S. at 599. "The discretion of Government officials to determine what" items to seize "is thus directly curtailed by the regulatory scheme." *Dewey*, 452 U.S. at 605; see also *National*

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[2] See also Admiralty Suppl. R. E(2)(a) (requiring the complaint to "state the circumstances from which the claim arises with such particularity that the defendant or claimant will be able, without moving for a more definite statement, to commence an investigation of the facts and to frame a responsive pleading").

Treasury Employees Union v. *Von Raab*, 489 U.S. 656, 667 (1989).

3. Petitioner does not dispute that it engages in a business that is so closely and comprehensively regulated by the federal government as to fall within the *Colonnade-Biswell* exception. Nor does petitioner assert that the warrantless inspections of its property violated the Constitution or that the government's actions in obtaining an *in rem* arrest warrant were unauthorized by the FDCA. Petitioner's sole argument is that the government's use of the FDCA's *in rem* arrest procedures in this case violated the Fourth Amendment because, in its view of the circumstances of this particular case, those procedures were not "necessary" to advance the government's interests under the FDCA, because government officials "waited 94 days" after the last regulatory inspection before seizing petitioner's drugs. Pet. 7.

The length of time elapsed between inspection and seizure in a particular case is, however, irrelevant to the issue of whether the government's actions are protected by the *Colonnade-Biswell* exception. "If a random, unannounced inspection does not violate [petitioner's] Fourth Amendment right of privacy," there is "no reason why the unannounced execution of a warrant under the Supplemental Rules would do so." Pet. App. A13. Nor is there reason to adopt a rule that would have the constitutional inquiry turn on a case-by-case analysis of whether federal officials will be able to obtain a judicial warrant without undermining administrative enforcement. Petitioner is willing to assume that "the regulatory *inspections* may have been necessary to further the regulatory scheme." Pet. 7 (emphasis added). Since this Court's decisions make clear that the government can seize

contraband discovered in the course of such inspections, see *Colonnade*, 397 U.S. at 72; *Biswell*, 406 U.S. at 312, there is no basis on which to conclude that a seizure subsequent to a warrantless inspection invades Fourth Amendment interests in a manner different from a seizure contemporaneous with a warrantless inspection. Compare *United States* v. *Jacobsen*, 466 U.S. 109, 120-121 (1984) (seizure of contraband by law enforcement was reasonable where prior to that seizure the owner's "privacy interest * * * had been largely compromised" by a private search); *United States* v. *Edwards*, 415 U.S. 800, 806-807 (1974). In short, as the court of appeals stated, there is no need to require the government "to brigade the seizure with an inspection in order to legitimize it." Pet. App. A13.

Petitioner also suggests that the subsequent seizure was unreasonable because it was "particularized." See Pet. 7, 9. But the fact that the government has identified specific items subject to seizure limits, rather than magnifies, the intrusion on petitioner's Fourth Amendment privacy expectations. Moreover, petitioner's suggestion is inconsistent with *Biswell*, which upheld the seizure of specific firearms discovered as the result of a warrantless government inspection. *Biswell*, 406 U.S. at 312-313. Indeed, it would be odd to conclude that the government does not need a judicial warrant to enter into and inspect a regulated commercial establishment when it has *no* particular reason to suspect noncompliance with regulatory obligations, but that it must obtain such a warrant when, as here, it has information that specific items are being held in violation of regulatory requirements—especially in light of the Fourth Amendment's stated preference for particularity in

government searches and seizures. U.S. Const. Amend. IV.

4. Petitioner also contends (Pet. 11-12) that the decision below conflicts with the Tenth Circuit's reasoning in *Winters* v. *Board of County Commissioners*, 4 F.3d 848 (1993), cert. denied, 114 S. Ct. 1539 (1994), which invalidated a police seizure of a stolen ring from an Oklahoma pawn shop. The *Winters* court, however, based its decision on its conclusion that the seizure of the ring was the result of "pretextual" inspection of the shop, which failed to give the police "a lawful right of access" to the seized property. 4 F.3d at 854; compare *Burger*, 482 U.S. at 717 n.27.

In this case, by contrast, it is undisputed that the seizure of petitioner's drugs resulted from a lawful administrative search of petitioner's premises, pursuant to the FDCA and the Supplemental Rules, which—unlike the Oklahoma statute in *Winters*—expressly authorize seizures of adulterated drugs without a judicial warrant. See 21 U.S.C. 334. In addition, the consequences from the delayed seizure of a ring are, to say the least, decidedly different from those presented by the failure to seize drugs that may be unfit or unsafe for their intended use.[3]

Petitioner also contends that the decision of the court of appeals conflicts with its prior decision in

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[3] The concerns expressed by the Tenth Circuit in *S & S Pawn Shop, Inc.* v. *City of Del City*, 947 F.2d 432, 441 (1991) (see Pet. 11)—a decision that actually upheld the facial constitutionality of the Oklahoma pawnshop inspection scheme—similarly related to allegations that specific pawnshop inspections "were conducted not as part of a pre-planned and dispassionate administrative procedure but instead pursuant to direct criminal suspicion."

United States v. *Device, Labeled "Theramatic"*, 641 F.2d 1289 (9th Cir. 1981) (*Theramatic I*), which invalidated the warrantless seizure of an allegedly misbranded medical device from a doctor's office under the FDCA. As the court of appeals explained, however, the seizure in *Theramatic I* "was effectuated by an impermissible invasion of the * * * right of privacy" of a physician whose business (unlike that of petitioner) was "not closely regulated by the FDA"; thus "[t]he *Colonnade-Biswell* exception did not apply" at all. Pet. App. A11-A12. And even if there were an intracircuit conflict within the Ninth Circuit, the matter would be more appropriate for the court of appeals, rather than for this Court, to resolve. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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